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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,132	08/26/2003	Joerg Schiewe	01-1394	3249
28501 7590 04/13/2009 MICHAEL P. MORRIS			EXAMINER	
BOEHRINGER INGELHEIM USA CORPORATION			DIXON, ANNETTE FREDRICKA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/648,132 SCHIEWE ET AL. Office Action Summary Examiner Art Unit Annette F. Dixon 3771 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 16 January 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-14.31.32 and 34 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-5.31.32 and 34 is/are rejected. 7) Claim(s) 6-14 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

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#### DETAILED ACTION

 This Office Action is in response to the request for continued examination filed on January 16, 2009. Examiner acknowledges claims 1-14, 31, 32, and 34 are pending in this application.

#### Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16 2009 has been entered.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filted in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filted in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1-5, 31, 32, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Fuchs et al. (6.708.846).

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As to Claims 1 and 31, Fuchs discloses a delivery device (Figures 1 and 2) for the delivery of a drug (13) in an aerosol of droplets (Column 1, Lines 20-33) by delivery of the drug (13) under pressure, comprising: a container cartridge (1) having a non-pressurized cylinder (12) therein, at rest, containing a single dose of the drug (13), a piston (14) in the cylinder (12), and an outlet end (19) opposite the inlet end (the opening for the cylinder 12, near element 82) having a dispensing facility and means for feeding the drug thereto (Column 2, Line 63 thru Column 3, Line 18); an elastic element (36) for the storage of a predetermined quantity of energy; a mobile element (30) to which the predetermined quantity of energy can be fed and which is coupled to a piston (14 via the actuation of the button 39) (Column 3, Lines 19-63), such that the energy can move the piston (14) and expose the single-dose of the drug (13) to a predetermined increase in pressure within the cylinder (12), and a means for the respective introduction and removal of the container cartridge (11) into and from an accommodation chamber (29) within the device (Figure 2, via 28).

As to Claims 2 and 32, Fuchs discloses the container cartridge (11) can be introduced into the accommodation chamber via an opening (28) in the housing wall of the device (Figure 1).

As to Claim 3, Fuchs discloses the container cartridge (11) can be introduced directly into its end-position in the device. As seen in Figure 2, the accommodation chamber (29) is the beginning and the end potion of the container cartridge (11).

As to Claim 4, Fuchs discloses the container cartridge (11), after its introduction into the housing opening has a transport cartridge (via the movement of 30, 31, and 34).

As to Claim 5, Fuchs discloses part of the housing wall (Figure 2) has a grip (33) which provides a holding means for accommodating the container cartridge. As seen in Figure 2, the button has a rotary knob with striations or grips thereon. Further as described, the movement of the grip (button 33) results in a change within the space located within the accommodation chamber (29). (Column 3, Lines 30-44 and 55-63).

As to Claim 34, Fuchs discloses a delivery device (Figures 1 and 2) for the delivery of a drug (13) in an aerosol of droplets (Column 1, Lines 20-33) by delivery of the drug (13) under pressure. Inherently, the medicament dispensed may be inhaled to a user.

## Allowable Subject Matter

5. Claims 6-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

# Response to Arguments

Applicant's arguments with respect to claims 1-14, 31 32, and 34 have been considered but are moot in view of the new ground(s) of rejection.

### Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon Examiner Art Unit 3771

./Annette F Dixon/ Examiner, Art Unit 3771

/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771